

What is claimed is:

1. An apparatus for making coated dosage forms comprising:

- a) a mold plate;
- b) a retention plate;

wherein the mold plate and retention plate define a mold cavity for enclosing a core and having a flow path defined at least in part by an interior surface of said mold plate and the core to be coated; and

c) a nozzle assembly for introducing a flowable material into said mold cavity to coat at least a first portion of said core with said flowable material, said nozzle assembly having a nozzle tip and valve body comprising a valve stem tip, wherein at least a portion of the valve stem tip or nozzle tip are constructed from or coated with a thermally insulative material.

2. An apparatus according to claim 1, wherein the valve body further comprises a valve stem as a distinct element that is constructed from a material having at least high thermal conductivity.

3. An apparatus according to claim 2, wherein the valve stem is constructed from a material having thermal conductivity at 23°C of at least 1200 BTU-in/ft²-hr-°F.

4. The apparatus according to claim 1, wherein the both the valve stem tip and nozzle tip are constructed from a polymeric material having low thermal conductivity.

5. The apparatus according to claim 3, wherein both the nozzle tip and valve stem tip are constructed from or coated with a material having a thermal conductivity at 23°C not greater than 2 BTU-in/ft²-hr-°F.

6. The apparatus according to claim 1, wherein the mold plate has an internal surface with protrusions projecting towards the interior of the cavity formed between the mold plate and the retention plate.

7. The apparatus according to claim 6, wherein the core rests upon a spring-biased stem and the protrusions are in contact with the surface of the core.

8. The apparatus according to claim 5 wherein core is in the form of a compressed tablet and the flowable material comprises a gelatin.

9. The apparatus according to claim 1, wherein said flowable material comprises a polymer.

10. The apparatus according to claim 1, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-containing mixtures, sugars, and low-moisture polymer solutions.

11. An apparatus for making coated dosage forms comprising:

- a) a first mold plate;
- b) a second mold plate;

wherein the first mold plate and second plate define a mold cavity for enclosing a core and having a flow path defined at least in part by an interior surface of said first mold plate and the core to be coated; and

- c) a nozzle assembly in said first mold plate and said second mold for introducing a flowable material into said mold cavity to coat at least a portion of said core with said flowable material, said nozzle assemblies having a nozzle tip and valve assembly comprising a valve stem tip, wherein at least a portion of the valve stem tip or nozzle tip are constructed from or coated with a thermally insulative material.

12. The apparatus according to claim 11, wherein the valve body further comprises a valve stem as a separate element that is constructed from a material having at least high thermal conductivity.

13. The apparatus according to claim 10, wherein both the nozzle tip and valve stem tip are constructed from or coated with a material having a thermal conductivity at 23°C not greater

than 2 BTU-in/ft²-hr-°F, and wherein the valve stem is constructed from a material having thermal conductivity at 23°C of at least 1200 BTU-in/ft²-hr-°F.

14. The apparatus according to claim 11, wherein said flowable material comprises a polymer.

15. The apparatus according to claim 11, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-containing mixtures, sugars, and low-moisture polymer solutions.

16. The apparatus according to claim 11, wherein said flowable material is a first flowable material and said mold cavity is a first mold cavity, said apparatus further comprising:

d) a second mold plate for retaining a core and a third mold plate that define a second mold cavity; and

e) a second nozzle assembly having a second nozzle tip and a second valve stem tip for introducing a second flowable material, wherein at least a portion of the second nozzle tip or second valve stem tip are constructed from or coated with a thermally insulative material, wherein said first mold plate and second mold plate are affixed to a common carrier and rotatably mounted onto said apparatus.

17. A method for making a dosage form comprising:

a) providing a core within a mold cavity formed between a mold plate and a retention plate;

b) injecting a flowable material through a nozzle assembly into said mold cavity to coat at least a first portion of said core with said flowable material, said nozzle assembly having a nozzle tip and valve assembly comprising a valve stem tip, wherein at least a portion of the valve stem tip or nozzle tip are constructed from or coated with a thermally insulative material.

18. The method according to claim 17, wherein said flowable material comprises a polymer.

19. The method according to claim 17, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-containing mixtures, sugars, and low-moisture polymer solutions.

20. The method according to claim 17, wherein said flowable material comprises a gelatin.

21. The method according to claim 17 further comprising:

- c) separating said mold plate and retention plate;
- d) rotating said mold plate while retaining the partially coated core into alignment with a second mold plate;
- e) sealing said mold plate and second mold plate to enclose the partially coated core within a second mold cavity;
- f) injecting a flowable material through a second nozzle assembly in said second mold plate into said second mold cavity to coat at least a second portion of said core with said flowable material, said second nozzle assembly having a second nozzle tip and second valve stem tip, wherein at least a portion of the second valve stem tip or second nozzle tip are constructed from or coated with a thermally insulative material.

22. The method according to claim 21 wherein the flowable material comprises a gelatin and at least one mold plate is made from a material having good thermal conductivity and is continually maintained during molding operations at a temperature below the softening point for the selected flowable material, and wherein the valve stem is constructed from a material having thermal conductivity at 23°C of at least 1200 BTU-in/ft²-hr-°F.

23. A method for making dosage forms comprising:

- a) providing within a mold cavity formed between a first mold plate and a second mold plate a core having a coating on a first portion thereof;
- b) injecting a flowable material into said mold cavity through a nozzle assembly provided in said first mold plate to coat at least a second portion of said core with said flowable material, said nozzle assembly having a nozzle tip and valve assembly comprising a valve stem

tip, wherein at least a portion of the valve stem tip or nozzle tip are constructed from or coated with a thermally insulative material.

24. The method according to claim 23 wherein the flowable material comprises a gelatin and at least one mold plate is made from a material having good thermal conductivity and is continually maintained during molding operations at a temperature below the softening point for the selected flowable material, and wherein the valve stem is constructed from a material having thermal conductivity at 23°C of at least 1200 BTU-in/ft²-hr-°F.

25. A dosage form produced according to claim 17 wherein the core is in the form of a compressed tablet.

26. The dosage form of claim 25 having a coating of hardened gelatin-containing material with an average thickness not greater than about 400 microns, more preferably about 100 to 300 microns.

27. A dosage form produced according to the method of claim 14 wherein the core is in the form of a compressed tablet.

28. The method according to claim 23, wherein said flowable material comprises a polymer.

29. The method according to claim 23, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-containing mixtures, sugars, and low-moisture polymer solutions.

30. The method according to claim 23, wherein said flowable material comprises a gelatin.

31. A method of making dosage forms, comprising the steps of:

- a) compressing a powder into a compressed core in a compression module;
- b) transferring said compressed core to a zero cycle molding module;

c) molding a flowable material around said compressed core in said zero cycle molding module; and

d) hardening said flowable material so as to form a coating over said compressed core;

wherein steps (a) through (d) are linked together such that essentially no interruption occurs between said steps.

32. The method of claim 31, wherein one or more of said steps is performed on a continuous basis.

33. The method of claim 31, wherein said powder contains a pharmaceutical active ingredient.

34. The method of claim 31, wherein said flowable material contains a pharmaceutical active ingredient.

35. The method of claim 31, wherein steps (a) through (d) are performed simultaneously, such that while coatings are being hardened on a first group of cores in step (d), flowable material is being molded around a second group of cores in step (c), a third group of cores are being transferred to said zero cycle molding module in step (b), and a fourth group of cores are being formed in step (a).

36. The method according to claim 31, wherein step (c) comprises the steps of:

(i) molding a first flowable material around a first portion of said compressed dosage form; and

(ii) molding a second flowable material around a second portion of said compressed dosage form.

37. The apparatus according to claim 36, wherein said flowable material comprises a gelatin.

38. The method according to claim 31, wherein said flowable material comprises a polymer.

39. The method according to claim 31, wherein said flowable material comprises a material selected from the group consisting of sucrose-fatty acid esters; fats, waxes, fat-containing mixtures, sugars, and low-moisture polymer solutions.
40. The method according to claim 31, wherein said flowable material comprises a gelatin.